VII. 510(k) Summary

Submitter	Corisen Group, Ltd. 575 Charring Cross Drive, Suite 100 Westerville, OH 43081 Telephone: 513-646-9878 Date Prepared: April 2, 2003
Device Proprietary Name	WORRY-REMOVER™ IRRIGATOR
Device Classification	DOUCHE APPRATUS, VAGINAL, THERAPEUTIC
Common/Usual Name	Vaginal Irrigator
Predicate Devices	La Joie Vaginal Cleaner Container (K000736); Peri-Bottle (K902830)
Device Description	The irrigating-bottle is hand-squeezed to force the cleaning solution to slowly and completely flow into the vaginal cavity. The one-way liquid valve permits the fluid to flow only from the bottle into the vaginal cavity but not back to the bottle, preventing contaminations of the solution and bottle. The one-way air valve permits air to flow into the bottle to prevent production of negative pressure within the bottle. The flow speed of the liquid is controlled by the user's hand. This system makes the process of vaginal irrigation much easier, neater, and more relaxing than using some other types of irrigators.
Intended Use	WORRRY-REMOVER™ IRRIGATOR is designed for use as a vaginal douche apparatus for general feminine hygiene applications.
Comparison to Predicate Device	The indication for use of WORRRY-REMOVER™ Irrigator are substantially equivalent to the previously cleared La Joie Vaginal Cleaner Container (K000736) and Peri-Bottle (K902830).
Conclusion	WORRRY-REMOVER™ Irrigator is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2003

Ms. Pamela Shen
Vice President
Corisen Group, Ltd.
575 Charring Cross Drive, Suite 100
WESTERVILLE OH 43081

Re: K030056
Trade/Device Name: WORRY-REMOVER™ Irrigator
Regulation Number: 21 CFR 884.5900
Regulation Name: Therapeutic vaginal douche apparatus
Regulatory Class: II
Product Code: 85 HED
Dated: March 10, 2003
Received: March 13, 2003

Dear Ms. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IV. Indication for Use

510(k) Number (if known): K030056

Device Name: WORRRY-REMOVER™ IRRIGATOR

Indications for Use:

The WORRRY-REMOVER™ IRRIGATOR is designed for use as a vaginal douche apparatus for general feminine hygiene applications.

(Please do not write below this line – continue on another page if needed)

Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter Use: ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030056